

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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| Applicant's or agent's file reference<br>21496-25-15P  | <b>FOR FURTHER ACTION</b>  |  |
|  | See item 4 below   |  |
| International application No.<br>PCT/US2004/041570   | International filing date ( <i>day/month/year</i> )<br>10 December 2004 (10.12.2004) | Priority date ( <i>day/month/year</i> )<br>12 December 2003 (12.12.2003) |
| International Patent Classification (8th edition unless older edition indicated)<br>See relevant information in Form PCT/ISA/237 |  |  |
| Applicant<br>USGI MEDICAL INC.   |  |  |

|  |   |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
|--|---|-------------------------------|--------------------------|---------------------|--------------------------|--|--------------------------|---------------------------------------|-------------------------------------|---|--------------------------|------------------------------------|--------------------------|--|-------------------------------------|--|
| <ol style="list-style-type: none"> <li>1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).</li> <li>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</li> </ol> <p style="margin-top: 10px;">In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.</p>   |   |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <ol style="list-style-type: none"> <li>3. This report contains indications relating to the following items:           <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 15%; text-align: center; padding-bottom: 5px;"> <input checked="" type="checkbox"/> </td> <td style="width: 85%;">Box No. I Basis of the report</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input type="checkbox"/> </td> <td>Box No. II Priority</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input type="checkbox"/> </td> <td>Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input type="checkbox"/> </td> <td>Box No. IV Lack of unity of invention</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input checked="" type="checkbox"/> </td> <td>Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input type="checkbox"/> </td> <td>Box No. VI Certain documents cited</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input type="checkbox"/> </td> <td>Box No. VII Certain defects in the international application</td> </tr> <tr> <td style="text-align: center; padding-bottom: 5px;"> <input checked="" type="checkbox"/> </td> <td>Box No. VIII Certain observations on the international application</td> </tr> </table> </li> <li>4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).</li> </ol> | <input checked="" type="checkbox"/>   | Box No. I Basis of the report | <input type="checkbox"/> | Box No. II Priority | <input type="checkbox"/> | Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | <input type="checkbox"/> | Box No. IV Lack of unity of invention | <input checked="" type="checkbox"/> | Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | <input type="checkbox"/> | Box No. VI Certain documents cited | <input type="checkbox"/> | Box No. VII Certain defects in the international application | <input checked="" type="checkbox"/> | Box No. VIII Certain observations on the international application |
| <input checked="" type="checkbox"/>  | Box No. I Basis of the report   |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input type="checkbox"/>   | Box No. II Priority   |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input type="checkbox"/>   | Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input type="checkbox"/>   | Box No. IV Lack of unity of invention   |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input checked="" type="checkbox"/>  | Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input type="checkbox"/>   | Box No. VI Certain documents cited  |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input type="checkbox"/>   | Box No. VII Certain defects in the international application  |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |
| <input checked="" type="checkbox"/>  | Box No. VIII Certain observations on the international application  |                               |                          |                     |                          |  |                          |                                       |                                     |   |                          |                                    |                          |  |                                     |  |

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| <p>The International Bureau of WIPO<br/>34, chemin des Colombettes<br/>1211 Geneva 20, Switzerland</p> <p>Facsimile No. +41 22 740 14 35</p> | <p>Date of issuance of this report<br/>12 June 2006 (12.06.2006)</p> <p>Authorized officer<br/><b>Ellen Moyse</b><br/>Telephone No. +41 22 338 89 75</p> |
|--|--|

**PATENT COOPERATION TREATY**

From the  
INTERNATIONAL SEARCHING AUTHORITY

To:  
JAMES M. HESLIN  
TOWNSEND AND TOWNSEND AND CREW LLP  
TWO EMBARCADERO CENTER, 8TH FLOOR  
SAN FRANCISCO, CA 94111-3834

**PCT**

REC'D 06 OCT 2005

WIPO

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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference

21496-25-15P

International application No.

PCT/US04/41570

International filing date (day/month/year)

10 December 2004 (10.12.2004)

04 OCT 2005

Priority date (day/month/year)

12 December 2003 (12.12.2003)

**FOR FURTHER ACTION**

See paragraph 2 below

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 17/08 and US Cl: 606/153

Applicant

USGI MEDICAL, INC.

1. This opinion contains indications relating to the following items:

|                                     |              |  |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I    | Basis of the opinion   |
| <input type="checkbox"/>            | Box No. II   | Priority   |
| <input type="checkbox"/>            | Box No. III  | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability   |
| <input type="checkbox"/>            | Box No. IV   | Lack of unity of invention   |
| <input checked="" type="checkbox"/> | Box No. V    | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/>            | Box No. VI   | Certain documents cited  |
| <input type="checkbox"/>            | Box No. VII  | Certain defects in the international application   |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application  |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US  
Mail Stop PCT, Attn: ISA/US  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Faxsimile No. (703) 305-3230

Authorized Officer

Julian W. Woo

Telephone No. 571-273-2975

Form PCT/ISA/237 (cover sheet) (January 2004)

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/41570

**Box No. I Basis of this opinion**

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

This opinion has been established on the basis of a translation from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

a sequence listing  
 table(s) related to the sequence listing

b. format of material

in written format  
 in computer readable form

c. time of filing/furnishing

contained in international application as filed.  
 filed together with the international application in computer readable form.  
 furnished subsequently to this Authority for the purposes of search.

3.  In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.  
PCT/US04/41570

**Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

|                               |                     |     |
|-------------------------------|---------------------|-----|
| Novelty (N)                   | Claims <u>39-55</u> | YES |
|                               | Claims <u>1-38</u>  | NO  |
| Inventive step (IS)           | Claims <u>45-55</u> | YES |
|                               | Claims <u>1-44</u>  | NO  |
| Industrial applicability (IA) | Claims <u>1-55</u>  | YES |
|                               | Claims <u>NONE</u>  | NO  |

2. Citations and explanations:

Claims 1-20, 22, and 27-38 lack novelty under PCT Article 33(2) as being anticipated by Adams (6,447,533). Adams discloses, in figures 12-15 and col. 8, lines 3-25, an apparatus or system and a method with the apparatus for forming a tissue fold in a tissue wall of a patient's hollow body cavity, where the apparatus includes a catheter (70a) or endoscopic device having a flexible tube, a tissue engaging assembly (84), and a tissue approximation device (connected to 84), where the tissue approximation device moves a first tissue contact point to a position proximal of a second tissue contact point to form the tissue fold; where the tissue approximation device moves the first tissue contact point, so that the second and a third tissue contact point are disposed on opposing sides of the tissue fold; where the apparatus includes an anchor delivery system with a flexible delivery catheter (70) configured to buckle into transverse alignment with the tissue fold, where the anchor delivery system includes a needle (60c), where the tissue engaging assembly (84) is configured to engage tissues as claimed, where the apparatus includes a shape-lockable guide tube(80), and where the method includes visualizing formation of the tissue fold with a visualization element (at 70).

Claims 14 and 21 lack novelty under PCT Article 33(2) as being anticipated by Matsui et al. (6,352,503). Matsui et al. disclose, in figures 44-47, a method of forming a tissue fold in a tissue wall of a patient's hollow body cavity, where first and second tissue contact points are endoscopically engaged to form the tissue fold, as well as an additional tissue fold.

Claims 22-26 lack novelty under PCT Article 33(2) as being anticipated by Kortenbach (6,086,600). Kortenbach discloses, in figures 2 and 11-15, a system for endoscopically forming a tissue fold within a hollow body organ, where the system includes an endoscopic device (18), a tissue engaging mechanism (42), an anchor delivery system (40), an articulable imaging device (2) or gastroscope, and a shape-lockable tubular member (12).

Claims 39-44 lack an inventive step under PCT Article 33(3) as being obvious over Adams in view of Matsui et al. Adams discloses the method substantially as claimed, but does not disclose endoscopically performing gastric reduction by approximating and securing a plurality of tissue folds, so that a stomach is partitioned into first and second chambers, and so that a first lumen has a volume in the range of 10-50 cubic centimeters. Matsui et al. teach, in figures 44-47, the partitioning of stomach into first and second chambers by the approximating and securing of a plurality of tissue folds. It would have been a matter of obvious design choice to form a plurality of tissue folds in order to partition the stomach and create more than one tissue fold for creating a valve for prevent gastric juice reflux.

Claims 45-55 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for performing a medical procedure within a hollow body organ, where the method includes, *inter alia*, forming a plurality of tissue folds as claimed in a patient's stomach, and where a cancer, lesion, or bleeding site on a tissue fold is treated as claimed.

Claims 1-55 meet the criteria set out in PCT Article 33(4), and thus an apparatus, a system, and a method for forming a tissue fold in a tissue wall of a patient's hollow body cavity have industrial applicability because the subject matter claimed can be made or used in industry.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/41570

**Box No. VIII Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the questions whether the claims are fully supported by the description, are made:

Claims 1-13 are objected to under PCT Rule 66.2(a)(v) as lacking clarity under PCT Article 6 because base claims 1 and 2 are indefinite for the following reason(s): First, second, and third tissue contact points of the patient's hollow body cavity are claimed as structural parts of the invention.